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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,964	02/02/2001	Kiyozo Asada	1333-DIV2-00	9656

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,964	ASADA ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 17 February 2004.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 95 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 95 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 06 January, 2004, has been entered.

Status of the Claims

Claim 95 is pending and claims 1-94, 96, and 97 have been canceled without prejudice or disclaimer.

35 U.S.C. § 112, Second Paragraph

Claim 95 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim has been amended to include limitations directed toward nucleic acids that hybridize to a complement of SEQ ID NO.: 26 under "highly stringent conditions." The hybridization parameters can vary considerably, even under "highly stringent" conditions. A number of parameters govern the stringency of the hybridization including the hybridization temperature, hybridization time, washing temperature, washing time, detergent concentration, monovalent cation concentration, G and C base composition of annealing nucleic acids, length of nucleic acid probe, concentration of helix-destabilizing agents (i.e., formamide), percentage of base mismatch, and pH. Changes in any of these parameters will affect the specificity of any given probe.

Thus, the precise parameters encompassed by the claim language are vague and nebulous.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 95 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claim has been amended to include polypeptides encoded by nucleic acids that hybridize to SEQ ID NO.: 26 under vaguely defined conditions. SEQ ID NO.: 26 is approximately 1,400 nt and encodes a 457 aa polypeptide. The only requirements of the claim language are that the nucleic acid of interest hybridize to SEQ ID NO.: 26 and that it must encode a polypeptide. The claim language does not place any additional structural or functional limitations on the nucleic acid or the polypeptide it encodes. Thus, the claims could encompass small or large fragments of SEQ ID NO.: 26, or nucleic acids with single or multiple nucleotide (and amino acid) additions, deletions, or insertions. Thus, the claims actually encompass a fairly large genus of polypeptides. The disclosure only describes the isolation and purification of the polypeptide represented by SEQ ID NO.: 5 and the single nucleic acid encoding it (SEQ ID NO.: 26). The disclosure does not discuss or describe the preparation of any other polypeptides related to this sequence.

The disclosure does not describe any fragments or functional equivalents of the claimed polypeptide.

In order to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of polypeptides encoded by any nucleic acid that hybridizes to the complement of SEQ ID NO.: 26. As previously set forth, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed

process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is

sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

As set forth *supra*, the claimed invention encompasses polypeptides of varying lengths carrying single or multiple amino acid additions, deletions, or substitutions. However, the disclosure fails to describe the molecular determinants modulating the functional properties of the claimed polypeptide. The recombinant protein described in the specification is large molecule of 457 amino acids. Thus, it is not readily manifest to the skilled artisan which peptidic fragments and variants will have the desired activity. Thus, there is nothing in the disclosure that would lead the skilled artisan to any particular amino acid or nucleotide sequence. Since the skilled artisan cannot predict or envision the structure of any of these polypeptide variants, the inventors clearly did not have possession of the claimed invention at the time of filing.

Response to Arguments

Applicants traverse and submit that adequate written support exists for the claimed invention. Reference was made to pages 19 and 28 of the disclosure wherein it was argued that adequate support was provided. These portions of the disclosure provide generic claim language that is directed toward identifying or screening for functional equivalents. However, this portion of the disclosure fails to disclose any polypeptide fragments derived from SEQ ID NO.: 5, or variants thereof, and the nucleic acids encoding them. Thus, it fails to provide adequate support for the claimed invention.

It was additionally argued by applicants that the claimed

invention has been drafted in accordance with the U.S.P.T.O. written description guidelines (see Example 9) and is fully supported by the disclosure. Applicants are reminded that while the guidelines provide useful suggestions for drafting claims, nevertheless, each application must be evaluated independently to ensure that it complies with the written description requirement. There are several differences between Example 9 in the guidelines and the claimed invention. First, the claimed invention does not place any structural or functional constraints on the polypeptide encoded by the nucleic acid. The claim simply stipulates "a polypeptide encoded by a gene which hybridizes to a complement of SEQ ID NO.: 26 under highly stringent conditions." There is no requirement that the polypeptide display any particular structure or activity. Second, the claimed invention clearly encompasses fragments and variants of the parent polypeptide encoded by the SEQ ID NO.: 26. Once again, the claims fail to provide any limitations concerning the structural and biochemical properties of the claimed polypeptides. Thus, the facts in this situation differ considerably from Example 9 in the guidelines.

Applicants also argue that a representative number of species were provided in the disclosure. Actually, the disclosure only provides a single example were SEQ ID NOS.: 5 and 26 are concerned. The disclosure does not describe the isolation and characterization of any polypeptide or nucleic acid variants of these sequences. Thus, the skilled artisan upon evaluating the disclosure and claims, would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Allowable Subject Matter

As previously set forth, the polypeptide consisting of SEQ ID NO.: 5 appears to free of the prior art. Appropriately drafted claim language directed toward this embodiment would be acceptable

(i.e., An isolated and purified polypeptide which facilitates binding of a retroviral vector to a target cell, wherein said retroviral vector is capable of transferring a gene into said target cell, wherein said polypeptide is a polypeptide consisting of SEQ ID NO.: 5.).

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

10 May, 2004